

SOUTH DAKOTA DEPARTMENT OF HEALTH
MINUTES OF PUBLIC HEARING

The Department of Health (DOH) convened a public hearing at 10:00 a.m. on Tuesday, October 12, 2021, at the State Health Laboratory, Room 102, 615 East Fourth Street, Pierre, South Dakota. A remote call-in option was also available. The purpose of the hearing was to conduct a public hearing to accept comments regarding the proposed amendment to Administrative Rule 44:67:04:12 regarding the informed consent form used by a physician to comply with the requirements of SDCL 34-23A-10.1(1).

Hearing Officer: Ali J. Tornow, Staff Attorney, South Dakota Department of Health, 600 East Capitol Avenue, Pierre, SD.

Persons in Attendance:

Ali J. Tornow, South Dakota Department of Health
Justin Williams, South Dakota Department of Health
Mitch Richter, appearing by phone

Exhibits: There was one (1) exhibit marked and received into evidence.

Exhibit A: Email from Mitch Rave of Sanford Health, regarding conditions applicable to carrying a child to term that may be added to the informed consent form.

Oral Testimony:

1. Justin Williams testified that the proposed amendment will bring the informed consent form in line with the statutory requirements of SDCL 34-23A-10.1 and 34-23A-10.5, and that the department has been working for some time on the language s to achieve the statutory requirements.

Adjournment: 10:11 a.m.

Respectfully submitted,

Dated: October 13, 2021



Ali J. Tornow

From: Rave, Mitchell <Mitchell.Rave@SanfordHealth.org>

Sent: Monday, October 4, 2021 2:53 PM

To: Valenti, Lynne <Lynne.Valenti@state.sd.us>

Cc: Malsam-Rysdon, Kim <Kim.Malsam-Rysdon@state.sd.us>; Brown, Corey <Corey.Brown@SanfordHealth.org>

Subject: [EXT] Proposed Rule Change RE: Abortion Informed Consent Form

Good afternoon Deputy Secretary,

Corey and I spoke with Sec. Malsam-Rysdon last week regarding the proposed rule change about the Abortion Informed Consent Form and she asked that we reach out to you with some of our comments/concerns. I shared the proposed rule change to our internal clinical group. Upon raising this up I was given some feedback by a few of our providers about some of the language that is included in the form to ensure that the form is clinically accurate. A few of the comments I received back were as follows.

"The proposed changes state that "carrying a baby to term is usually a safe and healthy process." That, of course, greatly depends on the patient's individual health and circumstances.

Is it possible for us to suggest a minor change, such as, "In an otherwise healthy person, carrying a pregnancy is usually a safe and healthy process"? Patients with hypertension, morbid obesity, thrombophilias, uncontrolled diabetes, cancer, lupus, and other serious health conditions are assuming fairly significant risk when they choose to carry a pregnancy.

Also, the most common causes of maternal mortality are not even listed here, including:

- Hemorrhage
- Cardiomyopathy
- Cardiovascular complications
- Blood clot
- Stroke
- Amniotic fluid embolus

Can we ask that those be added to the list?"

We realize that there is not a lot of flexibility for editing this document and understand that it may not be possible to pursue these changes. However, our providers felt it was important for us to lift up these concerns with the current language and offer up a few fixes. I would be happy to submit a written testimony or provide one via telephone at the call on Oct. 12th, but I wanted to bring these concerns to you first before bringing up them at the public forum. Please let me know if pursuing any of these changes is possible or if you require any other information from our end at Sanford Health.

Thank you for your time,

Mitchell Rave
Government Relations
Sanford Health

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October 18th 2021

Re: Proposed Amendments to the Informed Consent Form

To Whom it May Concern,

I write to you today on behalf of the American Civil Liberties Union of South Dakota to oppose the proposed amendments to the "Informed Consent for Abortion in South Dakota" form (ICA Form).



P.O. Box 1170
Sioux Falls, SD 57101
aclusd.org

This form presents misleading and inaccurate medical information to people seeking abortion care in a way that is clearly designed to discourage them from moving forward with the procedure. It presents six pages of potential risks associated with abortion and the proposed amendments only add one sentence about the potential risks associated with pregnancy. The choice to so disproportionately convey these risks is politically motivated and leaves people seeking reproductive healthcare without a meaningful opportunity for informed consent. The decision to over-emphasize complications associated with abortion as well as under-emphasize the risks associated with pregnancy to such an extreme degree is completely antithetical to the purpose of the informed consent process.

The proposed amendments also force doctors to provide false and misleading information to their patients about the potential to discontinue a drug induced abortion — an unproven and politically-motivated claim that has no basis in medical research. By forcing doctors to share misinformation that isn't backed up by credible science, and could be potentially harmful to patients seeking abortion care, politicians are eroding the trust between patients and their providers.

This manipulation of the informed consent process, which is a cornerstone of medical ethics, precludes people seeking abortions from enjoying a realistic freedom of choice. This form attempts to place politicians in-between doctors and their patients and coercively advance an anti-choice political agenda at the expense of the well-being of people seeking reproductive healthcare.

Reproductive freedom is a fundamental constitutional right grounded in the privacy protections of the First, Fourth, Fifth, Ninth, and Fourteenth Amendments of the United States Constitution. The ACLU holds that every person, as a matter of their right to the enjoyment of life, liberty, and privacy, should be free to determine whether and when to bear children. The decision about whether, when, or how to become a parent is one of the most important life decisions we make and is best made by each person with their family and faith. All South Dakotans should be able to do so without manufactured barriers and political interference.

We urge you to further revise the Informed Consent for Abortion in South Dakota form and consult with experts in reproductive health care to ensure that patients seeking abortion care are presented with accurate, relevant, and up-to-date medical information

that provides them with a meaningful opportunity for informed consent and a realistic freedom of choice.

Sincerely,



Jett Jonelis
Advocacy Manager
ACLU of South Dakota



P.O. Box 1170
Sioux Falls, SD 57101
aclusd.org



The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS
SOUTH DAKOTA SECTION

October 12, 2021

Re: Amendment of Proposed Rules Numbered §44:67:04:12

To Whom It May Concern:

As the leading experts in women's health in the state of South Dakota, the South Dakota section of the American College of Obstetricians and Gynecologists (SD ACOG) strongly recommends some alterations to the proposed rule amendment §44:67:04:12 pertaining to abortion consent.

Under 1-g:

1. Change the first line of the pregnancy risk paragraph to state that **"In an otherwise healthy person, carrying a pregnancy is usually a safe and healthy process"**, and remove the repeated statement at the end of the paragraph.
2. Include the most common causes of maternal mortality in the list of pregnancy risks as outlined by the CDC: Cardiovascular complications, hemorrhage, cardiomyopathy (a severe form of heart malfunction), sepsis, blood clot, stroke, and amniotic fluid embolus.
3. Strike "morning sickness" and replace with "a severe form of nausea and vomiting in pregnancy"

Reasoning:

The proposed changes state twice that "carrying a baby to term is usually a safe and healthy process." That, of course, greatly depends on the patient's individual health and circumstances. Patients with uncontrolled hypertension, morbid obesity, blood clotting disorders or bleeding disorders, uncontrolled diabetes, cancer, lupus, and other serious health conditions are assuming significant risk when they choose to carry a pregnancy. It is unethical to ignore or downplay these risks.

Second, the document has 6 pages describing risks associated with abortion and, in the proposed change, one sentence on the risks of continuing a pregnancy, and that sentence is incomplete. Medical evidence shows that the risk of maternal death is 14 times greater in carrying a pregnancy than in undergoing abortion. The most common causes of maternal death in pregnancy as outlined by the CDC are not listed in the document, and patients should be made aware of these risks when signing a consent form.

Finally, hyperemesis gravidarum is a very severe form of nausea and vomiting that can lead to extreme dehydration and electrolyte imbalances and may require hospitalization. It is a separate medical condition from "morning sickness".

Under Discontinuation of Drug Induced Abortion:

1. Change "it is still possible to discontinue a drug-induced abortion by..." to "it may be possible to continue a pregnancy by..."
2. Change "For more information, please contact your medical professional or healthcare provider" to "If you choose not take the prescribed dose of misoprostol, contact your physician or healthcare provider for expectant management."

Reasoning:

The line "discontinue a drug-induced abortion" erroneously suggests there is an active process one can take to stop an abortion, rather than correctly indicating that discontinuing *the regimen* makes the mifepristone less effective. This is confusing for patients and suggests they do not have to be sure about their decision to end a pregnancy.

Additionally, there is limited evidence suggesting mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage, and it is important to say that they should talk to a medical provider if they choose not to continue the regimen, not just "for more specific information".

We welcome any questions you may have pertaining to this recommendation. We can be reached at sdacog@gmail.com, or you can reach Dr. Schipper at 202-380-5050.

Respectfully submitted,

South Dakota ACOG

Erica Schipper, MD, Immediate Past Chair
Mark Ballard, MD, Chair
Amy Kelley, MD, Vice Chair

Sources:

1. Creinin, Mitchell D. et al. Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial. *Obstet Gynecol* 2020; 135(1):158-165.
2. CDC Maternal Mortality Surveillance:
<https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm>
3. Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. *Obstet Gynecol* 2012; 119: 215 – 9.



Planned Parenthood North Central States

The State of South Dakota Department of Health
Kim Malsam-Rysdon, Secretary of Health
600 East Capitol Avenue
Pierre, SD 57501-2536

October 15, 2021

RE: Amended Informed Consent for Abortion in South Dakota

Dear Secretary Malsam-Rysdon:

Over the course of several years, Planned Parenthood Minnesota, North Dakota, South Dakota (Planned Parenthood) has outlined our concerns with the South Dakota Department of Health's (DOH) "Informed Consent for Abortion in South Dakota" form (ICA Form). As experts in reproductive health care, and as the primary provider of abortions in the State of South Dakota for the last 27 years, our goal in continuing to provide comments on updates to the ICA Form is to ensure that South Dakotans receive accurate information from their health care providers, no matter what type of health care they seek.

We continue to believe that many elements of the ICA Form are medically inaccurate and outdated and would greatly benefit from input from current peer-reviewed, published research, up-to-date national health care guidelines and best practices, and participation from board-certified physicians who have experience providing reproductive health services.

To comply with current law, the South Dakota Department of Health has released an amended version of the ICA form, which we have carefully reviewed. Unfortunately, the concerns noted in previous correspondence remain unaddressed and the Amended ICA Form continues to contain misleading, as well as inaccurate information not supported by peer-reviewed, published medical research.

In response to HB1130 passed by the SD legislature in 2021, the amended ICA Form discusses the "Discontinuation of Drug Induced Abortion" (top of page 5). Not only is it unethical to require physicians to discuss medication abortion "reversal" and/or "discontinuation" with patients seeking abortion, neither practice is supported by the American College of Obstetricians and Gynecologists¹ (ACOG) nor the Society of Family Planning (SFP) due to patient safety concerns and the dearth of evidence available to support it as standard medical care. Moreover, medical professional groups, such as ACOG, SFP, and the American Medical Association, do not consider medication abortion "reversal" and "discontinuation" to be safe practices.

Additionally, given the lack of evidence for its use and these concerns for patient safety, medication "reversal" and/or "discontinuation" are not approved by the FDA. There is a single double-blind, placebo-controlled, randomized trial² (gold standard medical research) that was forced to halt enrollment early due to safety concerns related to abortion "reversal" and/or "discontinuation." This study concluded that patients in early pregnancy who use only mifepristone may be at high risk of significant hemorrhage.



Planned Parenthood North Central States

The AMA code of professional ethics requires that providers act for patient's welfare above self-interest, use sound medical judgement, and represent themselves and their expertise honestly.ⁱⁱⁱ Trust in the patient-physician relationship is fundamental to health care. Patients rely on the medical expertise of their providers to facilitate decision-making on the most appropriate options for their care, basing recommendations on sound evidence with intent to minimize risk while maximizing benefit.

Establishing this as the foundation for medical care is an essential component of patient trust and safety. Requiring that physicians discuss medication abortion "discontinuation" supplants medical expertise with the opinions of politicians. By submitting to this requirement, providers are subjecting patients to increased risk, thereby disrupting the fundamental trust that patients have in their medical providers and institutions.

The Amended ICA Form also includes newly proposed language regarding the "statistically significant medical risk associated with carrying [a pregnancy] to term compared to undergoing an induced abortion." (1-g, bottom of page 10.) Informed consent is an ethical cornerstone of medicine wherein physicians are obligated to provide patients with adequate, accurate and understandable information about a medical procedure. Through this vitally important practice, patients are given an opportunity to process information about a recommendation, ask questions, and weigh risks and benefits with the goal of voluntarily proceeding with treatment without coercion. Throughout the Amended ICA Form the risks of induced abortion are over-stated or blatantly false, while the real risks of continuing a pregnancy to term are understated and subverted with coercive statements such as "carrying a baby to term is usually a safe, healthy process for the mother." On page 4 the Amended ICA Form alludes to the fact that there have been no deaths reported related to abortion between 1987 to the present while the South Dakota Department of Health reports 72 maternal deaths between 2011 and 2020^{iv}. Minimizing risks of either option, induced abortion or continuing a pregnancy, does not allow patients an opportunity to make an informed decision. By utilizing the informed consent process to advance political agendas, the politicians in South Dakota only serve to delegitimize the informed consent process and introduce harm to the people of South Dakota.

The citizens of South Dakota deserve medically accurate, up-to-date and relevant information from their health care providers, regardless of their health care condition, the type of health care they seek or their geographic location. We hope DOH will further revise the Amended ICA Form to ensure that South Dakotans receive information that is relevant, medically accurate and supported by peer-reviewed, published medical research.

Sincerely,

671 Vandalia St
St Paul, MN 55114

Sarah Traxler, MD, MS, FACOG
Chief Medical Officer
Planned Parenthood North Central States

ⁱ <https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-supported-by-science>

ⁱⁱ Creinin M, et al. "Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A Randomized Controlled Trial," *Obstet Gynecol.* 2020;135:158–65.

ⁱⁱⁱ <https://www.ama-assn.org/delivering-care/ethics/patient-physician-relationships>

^{iv} <https://doh.sd.gov/statistics/maternalmortality.aspx>